IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	
	:	
A. BRADSHAW, ET AL.	:	
	:	Group Art Unit _____
Serial No.: (not yet designated -- this application a division of SN 08/644,101, which is a continuation of SN 08/057,322)	:	
	:	Examiner: (not yet designated)
Filed: Herewith	:	

Title: RADIOACTIVE SOURCE WIRE, APPARATUS AND TREATMENT METHODS

PRELIMINARY AMENDMENT

Commissioner of Patents and Trademarks
Washington, DC 20231

Please amend this application as follows:

In the Title:

Change the title to read: -- METHOD OF TREATING A BODY VESSEL OR DUCT WITH RADIATION FROM WITHIN THE LUMEN -- .

In the Specification:

Page 1, line 19, change "dose" to -- radioactivity level -- ;

line 21, change "dose" to -- radioactivity -- .

Page 2, line 14, change "regime" to -- regimen -- ;

line 19, correct the spelling of -- exposure --.

Page 3, line 9, change "dosage" to -- radioactivity level -- ;

line 13, correct the spelling of -- flexibility -- ;

Page 4, line 4, change "Solid" to -- A solid --.

line 8, delete "dosage or";

line 12, change "dose" to -- activity --;

line 18, change "dose" to -- activity -- .

Page 5, line 2, change "dose" to -- activity -- ;

line 9, correct the spelling of -- occlusion -- ;

lines 14, 16, and 20, change "reocclusion" (each occurrence) to -- re-occlusion -- ;

line 18, change "retreatment" to -- re-treatment -- .

Page 6, line 2, correct the spelling of -- substantial --.

Page 8, line 2, delete "the" (last occurrence).

Page 10, line 4, delete "and".

line 7, between "invention" and the period (.), insert the following:

-- ; and

FIG. 5A is a plan view of a centering balloon according to the present invention; and

FIG. 5B is a perspective sectional view of the centering balloon of **FIG. 5A** taken at line 5-5. --

line 15, correct the spelling of -- changes -- ;

line 19, correct the spelling of -- description -- .

Page 11, lines 6 and 8, change "dose" (each occurrence) to -- level -- .

Page 12, lines 16-18, delete the entire sentence beginning with "For example, in one form . . .";

line 19, after "be" insert -- flexed. --.

Page 14, line 21, delete "(a low dose wire)".

Page 15, line 1, change "dose" to -- level -- ; same line, delete "(a high dose wire)".

Page 17, line 13, delete "(dosage)";

line 15, between "the" and "vessel", insert -- blood --;

line 18, change "The" to -- Without perfusion, the -- .

Page 18, line 8, after "balloon" insert -- 60 (**FIG. 5A**) -- ;

line 11, correct the spelling of -- actually -- ;

line 13, after the first occurrence of "channel" insert -- 54 -- ; same line, after the second occurrence of "channel" insert -- 58 -- ; same line, after the third occurrence of "channel" insert -- 56 -- ;

line 14, after "balloon" insert -- (**FIG. 5B**) --.

Add the enclosed Abstract of the Disclosure as page 26 of the specification.

In the Claims:

Cancel claims 1-16, without prejudice, before calculating the filing fee for this application.

Add the following new claims:

-- **17.** (New) A method of treating the wall of a blood vessel from within the

lumen thereof, with a radiation catheter including a radiotherapy lumen, a longitudinally channeled distal balloon, and a balloon inflation lumen, comprising the steps of:

inserting said catheter into the vessel lumen until said balloon is adjacent a target site of the vessel wall to be treated;

inflating said balloon to substantially center said catheter radiotherapy lumen within the vessel lumen at the target site while allowing perfusion of blood past the inflated balloon through channels formed thereby;

advancing a radioactive source into said catheter radiotherapy lumen to position said source within a region thereof along a portion of the catheter occupied by said balloon; and

withdrawing said source after being positioned within said region for a predetermined interval of time.

18. (New) The method of claim **17**, wherein the step of inserting the catheter into the vessel lumen is performed by steering said catheter over a guide wire previously inserted into the vessel lumen past the target site.

19. (New) The method of claim **17**, wherein the step of advancing the radioactive source into the catheter radiotherapy lumen is performed by advancing a source wire having said radioactive source secured at its distal end.

20. (New) The method of claim **19**, including the step of using a super-elastic source wire with said distal radioactive source.

21. (New) The method of claim **17**, including selecting a radioactive source with a predetermined activity level, and setting said predetermined time interval in which the radioactive source is positioned within said region, to deliver a radiation dosage of from about 1,000 rads to about 1,500 rads to tissue in the vessel wall in proximity to the vessel lumen at the target site.

22. (New) The method of claim **17**, further including the step of removing the catheter from the vessel lumen after the radioactive source has been withdrawn.

23. (New) A method of treating a body duct with a centering catheter from within the lumen of the duct, which comprises:

inserting the centering catheter into the lumen of the body duct to position a centering device of said catheter at a site of the duct to be treated;

deploying said centering device of the catheter to position a radiotherapy lumen of the catheter at substantially the radial center of the lumen of the duct at said site;

advancing material having a predetermined level of radioactivity into said radiotherapy lumen of the catheter to a position at said site; and

retracting said radioactive material after a predetermined time interval at said site.

24. (New) The method of claim **23**, wherein the centering device is a balloon secured distally about the catheter with lobes forming channels along the distally secured portion, to position said radiotherapy lumen at substantially the radial center of the lumen of the duct at said site when the balloon is inflated for said deployment.

25. (New) The method of claim **23**, including inserting the centering catheter into the lumen of the duct over a guide wire previously inserted therein.

26. (New) The method of claim **23**, including advancing said radioactive material into the radiotherapy lumen of the catheter on a super-elastic wire.

27. (New) The method of claim **23**, including designating said predetermined radioactivity level and said predetermined time interval to produce a radiation dosage of from about 1,000 rads to about 1,500 rads to tissue in the wall of the duct in proximity to the lumen of the duct at said site.

28. (New) A method of inhibiting stenosis at a target site in a blood vessel, which comprises:

introducing radioactive material of predetermined radioactivity level at substantially the radial center of the lumen of the vessel at said site;

leaving said radioactive material substantially centered in the vessel lumen at said site for a predetermined period of time; and

immediately after said time period expires, removing the radioactive material from the site.

29. (New) The method of claim **28**, including introducing said radioactive material at substantially the radial center of the lumen of the vessel at said site through a radiotherapy lumen of a longitudinally fluted balloon catheter previously inserted into the vessel lumen and whose balloon has then been inflated for radially centering said radiotherapy lumen at said site and permitting blood flow past the inflated balloon.

30. (New) The method of claim **29**, including introducing the radioactive material through said radiotherapy lumen of the balloon catheter in a manner to maintain the radioactive material confined at substantially the radial center of the lumen of the vessel at said site.

31. (New) The method of claim **30**, wherein said radioactive material is confined within the distal end of a wire configured to enable rapid travel through the radiotherapy lumen of said balloon catheter to the target site.

32. (New) The method of claim **30**, wherein said predetermined radioactivity

level and said predetermined time period are computed to achieve delivery of from about 1,000 rads to about 1,500 rads to tissue in the wall of the duct in proximity to the lumen of the duct at said site.

33. (New) A method of inhibiting restenosis in a blood vessel at a narrowed region of the lumen thereof to be treated by an angioplasty procedure, which comprises the steps of:

performing the angioplasty procedure;

substantially immediately thereafter introducing radioactive material of predetermined radioactivity level for a predetermined interval of treatment time at substantially the radial center of the lumen of the blood vessel along said narrowed region at which said angioplasty procedure was performed; and

removing said radioactive material from the blood vessel after said treatment time interval has elapsed.

34. (New) The method of claim **33**, including maintaining said radioactive material at substantially the radial center of the vessel lumen at said region for the entirety of said treatment time interval without blocking the flow of blood through the vessel along said region.

35. (New) The method of claim **34**, including introducing and maintaining said

radioactive material at substantially the radial center of the vessel lumen at said region thereof through a radiotherapy lumen of a balloon catheter inserted into the vessel lumen and with its balloon inflated at said region to form channels for both the radial centering and blood flow.

36. (New) The method of claim **35**, including conveying the radioactive material through said radiotherapy lumen of the balloon catheter by means of an elongate member.

37. (New) The method of claim **33**, including establishing said predetermined radioactivity level and said predetermined treatment time interval to result in the delivery of a prescribed dosage of radiation to tissue in the vessel wall in said region.

38. (New) A therapeutic process for alleviating hyperplasia in a body duct, which comprises:

irradiating the wall of the duct with source material of predetermined radioactivity level positioned at substantially the radial center of the lumen of the duct at a preselected site; and

immediately after a predetermined period of irradiation has elapsed, removing the source material from said site.

39. (New) The method of claim **38**, including performing said irradiation with

said source material contained within a therapy lumen of a balloon catheter inserted into the lumen of the duct and with its balloon shaped when inflated at said site to form radial centering channels for said therapy lumen.

40. (New) A therapeutic process for alleviating hyperplasia in a fluid-carrying duct of a patient's body, which comprises:

irradiating the wall of the duct with source material of predetermined radioactivity level positioned at substantially the radial center of the lumen of the duct at a preselected site which has been subjected to trauma, while concurrently allowing passage of fluid through the duct past the position of the source material; and

immediately after a predetermined period of irradiation has elapsed, removing the source material from said site.

41. (New) The method of claim **40**, wherein irradiating the duct wall is performed by first inserting into the lumen of the duct a balloon catheter whose balloon is shaped to form inflation lobes along the catheter adapted to substantially radially center a lumen of the catheter when the balloon is inflated in the duct, positioning and then inflating said balloon at said site for said centering of the catheter lumen and to allow passage of fluid through channels between said lobes past the inflated balloon at said site, and thereafter conveying said source material through said catheter lumen to said site.

42. (New) The method of claim 41, including conveying said source material through said catheter lumen to said site on a super-elastic wire adapted to navigate curves in a path through the catheter lumen created by the duct.

43. (New) The method of claim 42, further including deflating and withdrawing said balloon catheter from the lumen of the duct after said removal of the source material.

44. (New) An angioplasty procedure which comprises:

opening a narrowed region in the lumen of a blood vessel of a patient to increase blood flow therethrough;

thereafter irradiating the wall of the vessel with a source of predetermined radioactivity level positioned at substantially the radial center of the opened lumen along the previously narrowed region, while concurrently allowing passage of blood through the vessel past the site of the radioactive source; and

after completing a predetermined period of irradiation, removing said source from the vessel.

45. (New) The angioplasty procedure of claim 44, wherein the step of irradiating the vessel wall is performed by first inserting into the lumen of the vessel a centering catheter having a distal portion of its length sized and shaped to substantially radially center a lumen of the catheter in the vessel while allowing said passage of blood at the

previously narrowed region, halting insertion of the centering catheter when said distal portion thereof is situated at the previously narrowed region, and then delivering said radioactive source through said catheter lumen to a desired location along said distal portion thereof.

46. (New) The angioplasty procedure of claim **45**, including delivering said radioactive source through said catheter lumen on a super-elastic wire.

47. (New) The method of claim **45**, further including withdrawing said centering catheter from the vessel lumen after removal of the radioactive source from the vessel.

48. (New) A method of inhibiting stenosis at a target site in a coronary artery of a patient's body, which comprises:

inserting a radiation catheter with a distally secured longitudinally fluted centering balloon through a portion of the patient's cardiovascular system until said balloon is at said target site;

inflating said balloon to substantially align a radiotherapy lumen of said catheter with the longitudinal axis of the coronary artery at said target site while securing said catheter thereat and enabling blood flow past the inflated balloon through longitudinal flutes thereof;

advancing the distal tip of a dummy wire through the radiotherapy lumen of the

catheter to said target site, from delivery apparatus coupled to the proximal end of said catheter, and retracting the dummy wire back into the delivery apparatus while retaining a measurement of the distance traveled by the distal tip of the dummy wire to reach said target site;

advancing a radioactive distal tip of a source wire of predetermined radioactivity level from said delivery apparatus through the radiotherapy lumen of the catheter the same distance traveled by the distal tip of the dummy wire for positioning at said target site;

retracting the source wire back into the delivery apparatus after a predetermined time interval has elapsed with the radioactive tip of the source wire positioned at the target site; and

deflating said balloon and removing the radiation catheter from the patient's body.

49. (New) The method of claim **48**, including using a super-elastic material for all but the radioactive portion of the source wire.

50. (New) The method of claim **49**, including selecting a nickel-titanium alloy as the super-elastic material.

51. (New) The method of claim **48**, including performing the steps of advancing and retracting the source wire through the radiotherapy lumen of the catheter from and to a

radiation-proof safe in said delivery apparatus.

52. (New) The method of claim **48**, including inserting said radiation catheter over a guide wire previously inserted into the cardiovascular system at least as far as the target site in the coronary artery, and

keying the coupling of the proximal end of the catheter to said delivery apparatus to restrain the catheter and guide wire from undergoing rotation in the cardiovascular system during performance of the method.

53. (New) The method of claim **48**, including predetermining values of said predetermined radioactivity level and said predetermined time interval to result in delivery of a dose of radiation in a range from about 1,000 rads to about 1,500 rads to tissue in the coronary artery wall in proximity to the radioactive tip at the target site prior to retracting the source wire therefrom.

54. (New) A method of inhibiting stenosis at a target site in a blood vessel, which comprises:

introducing a radiation catheter, having a radiotherapy lumen with a proximal opening and a distal sealed end and having a channeled centering balloon located on the catheter for placement adjacent the target site, over a guide wire into the lumen of the blood vessel until said centering balloon is positioned at the target site;

inflating said centering balloon through an inflation lumen of the radiation catheter to position said radiotherapy lumen of the catheter at substantially the radial center of the vessel lumen at the target site and to allow perfusion of blood past the inflated centering balloon through channels formed thereby;

advancing a source wire having a distal radioactive source of predetermined activity through said radiotherapy lumen of the catheter from the proximal opening thereof until the radioactive source is within a region of the inflated centering balloon at the target site; and

withdrawing the source wire from said radiotherapy lumen of the catheter at the end of a predetermined time interval of said radioactive source being positioned at the target site.

55. (New) The method of claim **54**, including selecting a super-elastic material for the non-radioactive portion of the source wire.

56. (New) The method of claim **55**, including selecting a nickel-titanium alloy as the super-elastic material.

57. (New) The method of claim **54**, including:

coupling the proximal end of the radiation catheter to an afterloader, and

performing the steps of advancing and withdrawing the source wire through the

radiotherapy lumen of the catheter from and to a storage location in said afterloader.

58. (New) The method of claim **57**, including:

threading the guide wire through a guide wire lumen of the radiation catheter eccentrically offset relative to said radiotherapy lumen as part of the step of introducing the radiation catheter over the guide wire, and

keying the coupling of the proximal end of the radiation catheter to the afterloader to restrain the catheter and guide wire from undergoing rotation in the blood vessel during performance of the method.

59. (New) The method of claim **54**, wherein said predetermined activity level of the radioactive source and said predetermined time interval in which the radioactive source is positioned at the target site are calculated to enable delivery of a dose of radiation in a range from about 1,000 rads to about 1,500 rads to tissue in the vessel wall in proximity to the vessel lumen at the target site.

60. (New) A method of treating the wall of a blood vessel, comprising:

advancing a guidewire to a treatment site in the blood vessel;

advancing a catheter having a guidewire lumen over the guidewire to the treatment site; and

advancing a radioactive source secured at the distal end of a super-elastic wire

through a working lumen of the catheter, the distal end of the working lumen being located proximal to the distal tip of the catheter.

61. (New) A method of treating the wall of a blood vessel, comprising:

advancing a guidewire to a treatment site in the blood vessel;

advancing a catheter having a guidewire lumen over the guidewire to the treatment site; advancing a radioactive source through a working lumen of the catheter, the distal end of the working lumen being located proximal to the distal tip of the catheter, and

using a centering catheter as said catheter to maintain the radioactive source at substantially the radial center of the lumen of the blood vessel after advancement of the source to the treatment site.

62. (New) The method of claim **61**, including using a centering catheter with at least one passageway for adequate blood flow through the vessel while said radioactive source is maintained at substantially the radial center of the vessel lumen.

63. (New) The method of claim **62**, including using a centering catheter having an inflatable centering balloon with channels for enabling both the radial centering of and blood flow past the catheter. --

REMARKS

This application is a division of co-pending application Serial No. 08/644,101, which is a continuation of application Serial No. 08/057,322.

The specification has been amended to re-introduce the corrections made in both parent applications '322 and '101, and to add **FIGS. 5A** and **5B** which correspond to drawings that were added initially in the '322 application in response to the examiner's objection under 37 C.F.R. § 1.83(a).

Original claims 1-16 have been canceled without prejudice, and new claims 17-63 have been added, corresponding to claims previously submitted in the '101 application.

Early and favorable action on this divisional application is solicited.

Respectfully submitted,

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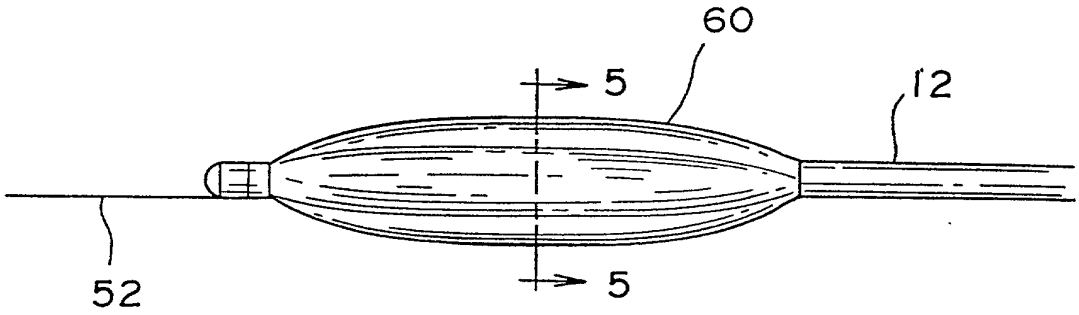

FIG. 5A

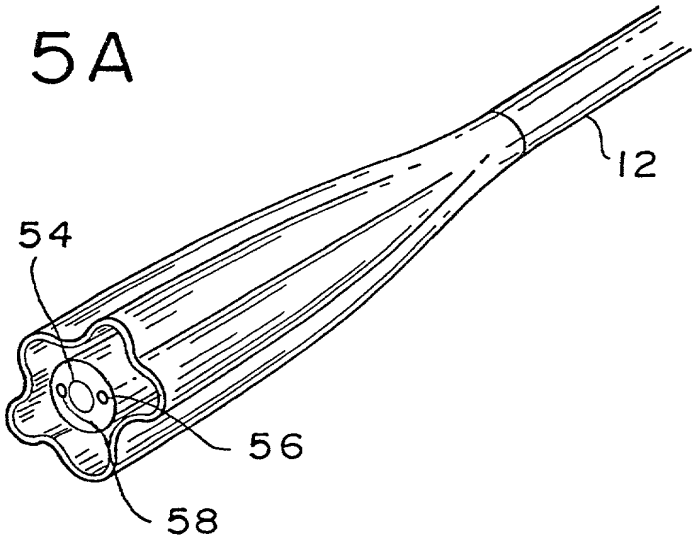

FIG. 5B